REMARKS

The drawings are amended, per the attached Submission, to overcome a few noted informalities contained therein. New Replacement Sheets of formal drawings, accompany this Submission, incorporate all of the requested drawing amendments. If any further amendment to the drawings is believed necessary, the Examiner is invited to contact the undersigned representative of the Applicant to discuss the same.

The above newly amended paragraphs of the specification overcome some informalities noted in the specification on file. The undersigned avers that the newly amended paragraphs of the specification do not contain any new subject matter.

Claim 10 is objected to for the reasons noted in the official action. The above requested claim amendments are believed to overcome all of the raised informalities concerning this case. If any further amendment to any of the pending claims is believed necessary, the Examiner is invited to contact the undersigned representative of the Applicant to discuss the same.

Claims 6 and 11 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons noted in the official action. The inadequate written description rejection is acknowledged and respectfully traversed in view of the following remarks.

Claims 6 and 11 have been amended to recite the feature of the outer tube being of such a size that the catheter is insertable into a blood vessel. The Applicant believes that paragraph [0046] of the specification provides more than adequate disclosure for inclusion of this feature into the claims. This paragraph states that "the catheter is inserted into a blood vessel from outside the body" such that the distal end thereof reaches into the heart. As the catheter comprises the outer tube and the outer tube is the outermost surface of the catheter, at least at the distal end, the Applicant contends that the outer must be of such a size that the catheter can be inserted into a blood vessel.

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons noted in the official action. The rejected claims are accordingly amended, by the above claim amendments, and the presently pending claims are now believed to particularly point out and distinctly claim the subject matter regarded as the invention, thereby overcoming all of the raised § 112, second paragraph, rejections. The entered claim amendments are directed solely at overcoming the raised indefiniteness rejections and are not directed at distinguishing the present invention from the art of record in this case.

Claims 6-9, 11, 12 and 16 are rejected, under 35 U.S.C. § 103(a), as being unpatentable over Evard et al. `251 (U.S. Patent No. 5,536,251) in view of Kratsch et al. `350 (U.S. Patent No. 5,478,350). The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the above amendments and the following remarks.

The claims of the application relate to a catheter that is to be inserted from outside of a body into a coelom and such that the distal end of the catheter reaches a target region while a proximate end of the catheter remains outside of the body. The catheter comprises an outer tube that is sized such that the distal end of the catheter can be inserted into a blood vessel. A first inner tube of the catheter is located within the outer tube and contains a forceps mechanism and an operating linkage that is constrained within the first inner tube in a closed position. A second inner tube of the catheter is also located within the outer tube and contains an injection mechanism. A guide wire tube is located within the outer tube and is parallel to the forceps mechanism and the injection mechanism. The guide wire tube accommodates a guide wire. The forceps mechanism has a first handling portion at the proximate end of the catheter and a grasping portion at the distal end of the catheter. The grasping portion is configured to open and close in conjunction with manipulation at the first handling portion, and is capable of holding the target region accessed by the catheter while at least a leading end of the distal end of the outer tube remains inserted within the blood vessel. The injection mechanism has a

second handling portion at the proximate end, and an injection needle at the distal end. The injection needle is configured to move forward to protrude from the distal end, and to move back into a retracted position, stored inside of the distal end. The injection mechanism is capable of puncturing the target region with the injection needle and injecting injectant into the target region. For this, the injection mechanism communicates with an injectant storage that is located at the distal end of the catheter such that manipulation at the proximate end of the catheter pressurizes the injectant storage and forces a flow of the injectant from the injectant storage and to the injection needle.

Now turning to the references, Evard et al. `251 relates to thoracoscopic devices that are used in arresting the heart. These device includes a clamping device 110 with an outer shaft 66 and an inner shaft 72 in which a pair of jaw extensions 78, 80 are disposed. The distal end of the jaw extensions 78, 80 have jaws 82, 84. The jaw extensions 18, 80 can be controlled at a proximal end thereof so as to slide to and fro in relation to the distal end such that the jaws 82, 84 open and close and can be used to clamp an aorta A.

The outer shaft 66 also encloses an inner sleeve 112 which provides a lumen 118 for a delivery tube 120 that has a needle 124 attached thereto. The distal end of the delivery tube 120 retains a retains a staple 126 that is initially held in an open state within the lumen 118 as shown in Fig. 6A. An actuation button 140, located at the proximal end of the inner sleeve 112 and device 110, biases the delivery tube 120 such that the needle 124 penetrates the wall of the aorta A. At this point a cardioplegic fluid is passed from a proximal end 146 of the delivery tube 120 to the needle 124 and into the aorta A. It should be noted here that the fluid passes from the proximal end 146 of the delivery tube 120, which is located at the proximal end of the device 110, to the opposite distal end of the delivery tube 120, which is located at the distal end of the device 110.

When injection of the fluid is complete a release button 162 is pressed which retracts the inner sleeve 112 such that the staple 126 is forced out of the lumen 118 where it then penetrates an aortal A, see Fig. 6B and closes thus clamping to the wall of the aorta A, see Fig. 6C.

The claims of the application are distinct from the teachings of Evard et al. `251 for a number of reasons in addition to those noted by the Examiner in the official action. For instance, Evard et al. `251 fails to teach a guide wire tube located within the outer tube that is parallel to the forceps mechanism and the injection mechanism and which accommodates a guide wire that is used for inserting a catheter into coelom.

Furthermore, Evard et al. `251 fails to teach an injectant storage that is located at the distal end of the catheter and communicates with the injection mechanism such that manipulation of the injection mechanism, at the proximate end of the catheter, pressurizes the injectant storage which forces the injectant to flow from the injectant storage to the injection needle.

Turning now to the reference of Kratsch et al. `350, this reference relates to a rack and pinion handle for endoscopic instruments. The rack and pinion handle (actuator mechanism 18, 118) is coupled to ends of a coil 12 and a push rod or wire 16. The coil 12 forms a lumen 14 through which the push rod 16 extends. The coil 12 and the push rod 16 span the length of a steel sleeve 64 and are coupled to an effector assembly 20 at their distal ends in such a manner that the effector assembly 20 is responsive to reciprocal movement to the push rod 16 relative to the coil 12.

The effector assembly 20 includes a clevis 56 and a pair of effectors 58, 59 and is designed such that when the actuator mechanism 18, 118 is actuated the coil 12 and the push rod 16 slide in relation to each other. Depending on the relative sliding motion between the coil

12 and the push rod 16, the pair of effectors 58, 59 either open or close, that is they either apply a clamping force between them or release the clamping force between them.

The claims of the application are distinct from the teachings of Kratsch et al. `350 for the same reasons discussed above in relation to Evard et al. `251. Specifically, Evard et al. `251 fails to teach a guide wire tube located within the outer tube that is parallel to the forceps mechanism and the injection mechanism and which accommodates a guide wire that is used for inserting a catheter into coelom. Evard et al. `251 also fails to teach an injectant storage that is located at the distal end of the catheter and communicates with the injection mechanism such that manipulation of the injection mechanism, at the proximate end of the catheter, pressurizes the injectant storage which forces the injectant to flow from the injectant storage to the injection needle. As such, all of the raised rejections related to the combination of Evard et al. `251 and Kratsch et al. `350 should be withdrawn at this time in view of the above amendments and remarks.

Claims 13-15 and 18 are rejected, under 35 U.S.C. § 103(a), as being unpatentable over Evard et al. `251 and Kratsch et al. `350 in view of Clement et al. `384 (U.S. Patent No. 5,350,384). While claim 17 is rejected, under 35 U.S.C. § 103(a), as being unpatentable over Evard et al. `251 and Kratsch et al. `350 in view of (U.S. Patent No. 5,376,075). The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the above amendments and the following remarks.

The Applicant acknowledges that the additional references of Clement et al. `384 and Haughton et al. `075 may arguably relate to the features indicated by the Examiner in the official action. Nevertheless, the Applicant respectfully submits that the combination of the base references of with this additional art of still fails to in any way teach, suggest or disclose the above distinguishing features of the presently claimed invention. As such, all of the raised rejections should be withdrawn at this time in view of the above amendments and remarks.

In order to emphasize the above noted distinctions between the presently claimed invention and the applied art, the independent claims of this application now recite the features of "a guide wire tube is located within the outer tube *parallel* to the forceps mechanism and the injection mechanism, the guide wire tube accommodating a guide wire. . .the injection mechanism communicating with an injectant storage that is located at the *distal end* such that manipulation at the proximate end pressurizes the injectant storage and forces a flow of the injectant from the injectant storage and to the injection needle". Such features are believed to clearly and patentably distinguish the presently claimed invention from all of the art of record, including the applied art.

If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejections should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejections or applicability of the Evard et al. `251, Kratsch et al. `350, Clement et al. `384 and/or Haughton et al. `075 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

In view of the foregoing, it is respectfully submitted that the raised rejections should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objections or requirements, as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,

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FIG.2A

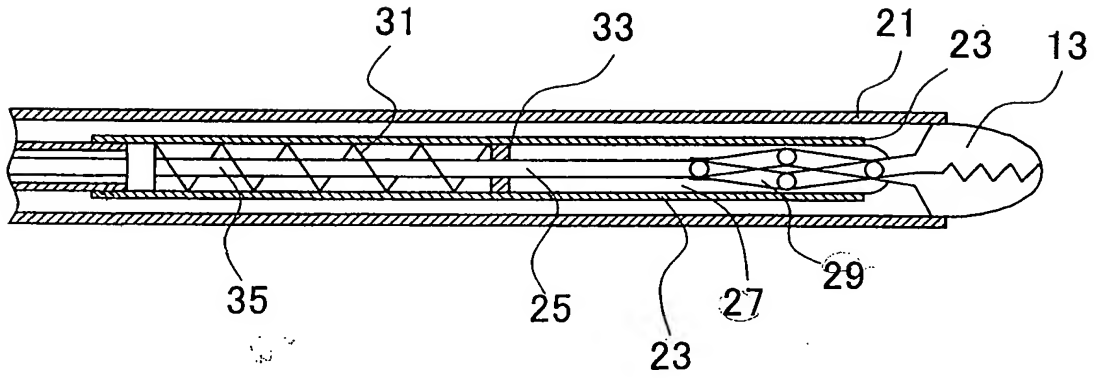

FIG.2B

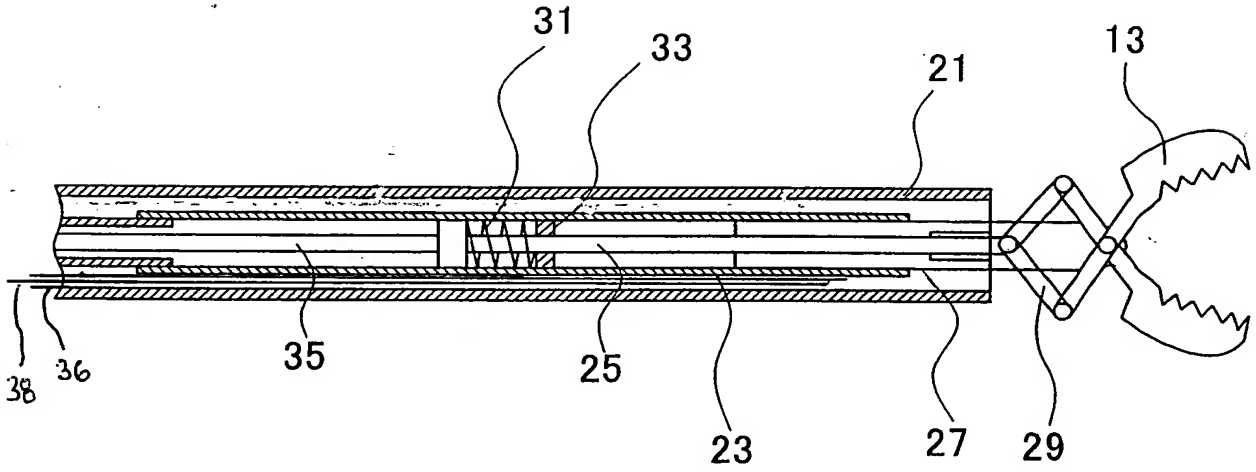

FIG.3A

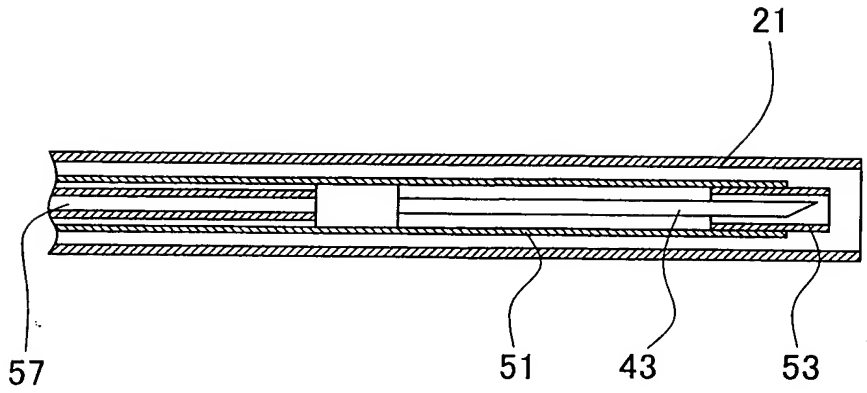

FIG.3B